



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/497,422 02/03/00 BERRY

S ARC2914R1

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HM12/1228

EXAMINER

FUBARA, B

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

12/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/497,422

Applicant(s)

BERRY ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Paper No. 7.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Examiner acknowledges paper number 7 filed 11/6/00.

Claim Rejections - 35 USC § 103

Rejection of claims 1-33 and 35-38 under 35 U.S.C. 103(a) is maintained as addressed in paper number 4.

1. Applicants' arguments filed 11/06/00 have been fully considered but they are not persuasive. The claimed invention is obvious over the prior art of record as addressed in paper number 4.

Response to Arguments

Applicants argue that there is no motivation or suggestion to combine or to modify the cited references. Applicants argue that Roorda et al. in column 2, lines 15-21 states that particles of biologically effective agent microencapsulated in a diffusion-limiting shell are difficult to manufacture and that it is difficult to control the release rate of the agent from the shell. It is the examiner's position that the instant invention is obvious over the references on record. Knepp et al. discloses a delivery vehicle comprising proteins, peptides, hormones, non-ionic surfactants, sucrose, raffinose, sorbitol, dextran, buffers and mineral oil. Nuwayser teaches a viscous delivery vehicle comprising biodegradable polymer, glycerol, and microparticles of hormones, steroids and antibacterial agents. Roorda et al. teaches viscous delivery vehicle comprising sorbitol, anti-bacterial agents, antiviral, anti-inflammatory and tissue regeneration agents, polyvinylpyrrolidone and polylactic/glycolic acid. Nuwayser and Roorda et al. teach viscous delivery vehicles comprising antibacterial agents and Nuwayser's vehicle in addition comprises hormones and steroids. Knepp et al. teaches a delivery vehicle comprising

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peptides, proteins, hormones and steroids. The suggestion or motivation stems from the fact that all three references teach delivery vehicles comprising antibacterial agents (Roorda and Nuwayser) and hormones and steroids (Nuwayser and Knepp et al). Thus there is reasonable expectation of success for a delivery vehicle comprising sorbitol, anti-bacterial agents, antiviral, anti-inflammatory and tissue regeneration agents, polyvinylpyrrolidone and polylactic/glycolic acid, proteins, peptides, hormones, non-ionic surfactants, sucrose, raffinose, sorbitol, dextran, buffers, mineral oil, biodegradable polymer, glycerol, and microparticles of hormones and steroids.

Examiner disagrees with applicants that Roorda et al. teaches away from the polymer coated active agent of Nuwayser. In the section cited by the applicant, that is column 2, lines 15-21, Roorda et al. points out one of the solutions offered to improve the teachings of the prior and further states the difficulty associated with that solution. Specifically, Roorda et al. teaches that the particle size influences the release rate of the particles from the vehicle and suggests that one can select a particle size to achieve a desired release rate, and polymer and particle concentration for the desired vehicle viscosity. See paper number 4.

The expected result from combining the teachings of the cited references on record is a non-aqueous uniform bio-compatible viscous delivery vehicle for suspending and delivering beneficial agents at a release rate that is determined by the choice of particle size.

Therefore, it is the position of the examiner that the instant invention is obvious over the cited references of record. Knepp et al. (page 14, lines 11) teaches that it is normal practice to include ascorbic acid, anti-oxidant in dilute aqueous peptide and protein formulations and also

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that formulation of dry protein or nucleic acid powders is well known in the art (page 17, line 30). It is therefore prima facie obvious to include anti-oxidant in the formulation.

The objection to claim 34 is maintained.

2. Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
December 23, 2000

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 4600